ISRCTN23220202 https://doi.org/10.1186/ISRCTN23220202

Phase I trial HMR code: 23-006

Submission date 26/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/02/2024	**Overall study status** Deferred	
Last Edited 09/02/2024	**Condition category** Other	

Plain English summary of protocol
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

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Additional identifiers

Integrated Research Application System (IRAS)
1008812

Protocol serial number
HMR code: 23-006

Study information

Scientific Title
Phase I trial HMR code: 23-006 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 21/12/2023, Harrow Research Ethics Committee (2 Redman Place, Stratford , London, E20 1JQ , United Kingdom; +44 (0)207 1048154; harrow.rec@hra.nhs.uk), ref: 23/LO /0809

2. approved 04/01/2024, MHRA (10 South Colonnade, Canary Wharf, London , E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 04854/0225/001-0001

Study design

First-in-human safety, pharmacokinetics, and pharmacodynamics trial in up to 168 healthy volunteers

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
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Interventions
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Key secondary outcome(s))
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Completion date
08/11/2025

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
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Date of first enrolment
13/02/2024

Date of final enrolment
08/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
HMR
Cumberland Avenue
Park Royal
London
United Kingdom
NW10 7EW

Sponsor information

Organisation
Gedeon Richter (Hungary)

ROR
https://ror.org/0033rtn64

Funder(s)

Funder type
Industry

Funder Name
Gedeon Richter

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Hungary

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available